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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,612	10/31/2003	Eric W. Leopold	MICRU:64933	9933

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FULWIDER PATTON
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
HOUSTON, ELIZABETH	
ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,612	LEOPOLD ET AL.	
	Examiner	Art Unit	
	Elizabeth Houston	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/10/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *25-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed..

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *022805*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, drawn to a stent, in the reply filed on 10/10/06 is acknowledged.

2. Claims 25-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/10/06.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the following must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

a. A predeployed compressed configuration that is substantially flattened as in claim 2

b. A cross section in the shape of a polygon or modified polygon having at least one straight portion as in claim 4

c. The deployed configuration varies in cross-sectional area along the longitudinal axis as in claim 5

d. The frame varies in pitch along the longitudinal axis as in claim 6

e. The windings have a variable diameter over the length of the device as in claim 11

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "the helical windings comprise a series of 6 alternating zigzag bends" as in claim 14.

Claim Objections

3. Claim 4 and 8 are objected to because of the following informalities: claims limitations need further clarification

f. Claim 4 states that the cross section is formed in the shape of a polygon or modified polygon having at least one straight portion. There is no description in the specification nor is there any drawing to understand exactly what the applicant intends.

g. Claim 8 is unclear as to what is meant by "helical windings have a range of pitch to provide wire coverage of the inner surface area of the target site being treated of between about 7% and 40%. It is unclear what the percentage is being applied to or compared to.

4. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1-17 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin (USPN 6,520,986).**

7. Martin discloses an intravascular flow modifier and reinforcement device comprising a generally cylindrical frame formed of elongate resilient wire configured as a series of helical windings (8). The device has a flattened (relative to the deployed configuration) pre-deployed configuration for placement and a deployed configuration having sharp alternating zigzag bends (16). The frame has a cross section in the shape of a modified polygon (Fig. 3A and B) with a straight portion (6). The cross sectional area or diameter varies along the longitudinal axis (Fig. 13A). The helical windings vary in pitch along the longitudinal axis (Fig. 6). The helical windings have a range of pitch to provide wire coverage of the inner surface area of the target site being treated of between about 7% and 40%. The zigzag bends have an angle less than about 120 degrees. The helical windings comprise a series of 4-8 alternating bends that includes either 4 or 6 bends (Fig. 7). The stent is made of superelastic shape memory material that is nitinol (Col 10, lines 45-65). The device is formed by laser cutting (Col 9, line 6).

8. **Claims 1-3, 6-10, 12-17 and 23 are rejected under 35 U.S.C. 102(b) as being Das by (USPN 5,554,181).**

9. Das discloses an intravascular flow modifier and reinforcement device comprising a generally cylindrical frame formed of elongate resilient wire configured as a series of helical windings (10). The device has a flattened (relative to the deployed configuration) pre-deployed configuration for placement and a deployed configuration having sharp alternating zigzag bends (24 and 26). The helical windings have a range of pitch to provide wire coverage of the inner surface area of the target site being

treated of between about 7% and 40%. The zigzag bends have an angle less than about 120 degrees. The helical windings comprise a series of 4-8 alternating bends that includes either 4 or 6 bends (see Fig. 3; Col 7, line 31-32). The wire is made of nitinol, which is shape memory and superelastic (Col 3, line 61-63). Regarding claims 6 and 10, the windings of the frame vary in pitch when the device is delivered to a tortuous vessel. Although the intertwining (18) is meant to prevent stretching, the opposite side of the stent will still have the capability to stretch and bend. Therefore it is inherent that when the stent is placed in a vessel with a sharp bend, the pitch or spacing between the windings located toward the middle of the bend will be greater than the pitch or spacing of the windings toward either end of the stent.

10. **Claims 1-17 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiktor (USPN 5,653,727).**

11. Wiktor discloses an intravascular flow modifier and reinforcement device comprising a generally cylindrical frame formed of elongate resilient wire configured as a series of helical windings (2b-f). The device has a flattened (relative to the deployed configuration) pre-deployed configuration for placement and a deployed configuration having sharp alternating zigzag bends (3b,c). The frame has a cross section in the shape of a modified polygon with a straight portion (Fig. 6). The cross sectional area or diameter varies along the longitudinal axis (as seen in Fig. 5 when delivered to a vessel that may have some tapering). The helical windings have a range of pitch to provide wire coverage of the inner surface area of the target site being treated of between about

7% and 40%. The zigzag bends have an angle less than about 120 degrees. The helical windings comprise a series of 4-8 alternating bends that includes either 4 or 6 bends (Fig. 7). The stent is low memory material that is stainless steel (Col 3, line 63). Regarding claims 6 and 10, the windings of the frame vary in pitch the windings of the frame vary in pitch when the device is delivered to a tortuous vessel. Although the intertwining (18) is meant to prevent stretching, the opposite side of the stent will still have the capability to stretch and bend. Therefore it is inherent that when the stent is placed in a vessel with a sharp bend, the pitch or spacing between the windings located toward the middle of the bend will be greater than the pitch or spacing of the windings toward either end of the stent. The stent is made of superelastic shape memory material that is nitinol (Col 11, line 2).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. **Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Ferrera (USPN 6,168,570).**

14. **Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiktor in view of Ferrera (USPN 6,168,570).**

15. **Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Das in view of Ferrera (USPN 6,168,570).**

16. Martin, Wiktor and Das disclose the claimed invention above substantially as claimed except for the wire comprises a stranded cable that is radiopaque.

17. Ferrera discloses a micro-strand cable for use in a stent having a strand of radiopaque material to provide radiopaque markings during therapeutic treatment. Ferrerra teaches that incorporating a radiopaque strand is an advantage because it allows the device to be easily seen in the body and avoids the need to add additional markers to the outside of the device.

18. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate wire that has radiopaque strands or markers into the stent in order to enhance the radiopacity of the stent so that it can be easily tracked during deployment. It is well known in the art to incorporate radiopacity into stents to easily locate them and to ensure delivery to the correct location. Ferrera offers the motivation. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

19. **Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Steinke (USPN 6,244,626).**

20. **Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiktor in view of Steinke (USPN 6,244,626).**

21. **Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Das in view of Steinke (USPN 6,244,626).**

22. Martin, Das and Wiktor disclose the claimed invention above substantially as claimed except for a coating.

23. Steinke discloses coating a stent with Parylene in order to provide a lubricious surface, to prevent corrosion and to reduce acute thrombosis.

24. It would have been obvious to one having ordinary skill in the art at the time of the invention coat the stent with a corrosion resistant material such as Parylene since it enhances the properties of the stent by preventing corrosion of the metal while at the same time reducing thrombosis at the treatment site. Steinke offers the motivation. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

25. **Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Andreacchi (USPN 6,679,980).**

26. **Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wiktor in view of Andreacchi (USPN 6,679,980).**

27. **Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Das in view of Andreacchi (USPN 6,679,980).**

28. Martin, Das and Wiktor disclose the claimed invention above substantially as claimed except for treating the stent with chemical electropolishing.

29. Andreacchi discloses a stent that is electropolished in order to provide a protective corrosion-resistant oxide layer on the stent surface.

30. It would have been obvious to one having ordinary skill in the art at the time of the invention to treat the stent with electropolishing since it enhances the properties of the stent material by protecting the material from corrosion. Andreacchi offers the motivation. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

31. **Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wiktor.**

32. **Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Das.**

33. As to claim 24, Wiktor and Das teach an intravascular flow modifier and reinforcement device made of elongate resilient wire but is silent as to how the device is made. The claimed phrase "laser cutting" is being treated as a Product by Process limitation, that is the device is formed by laser cutting. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

34. Thus, even thought Wiktor and Das are silent to the process used to form the device, it appears that the product disclosed by Wiktor and Das would be the same or similar as that claimed; especially since both applicant's product and the prior art product a stent made of elongate resilient wire with helical windings having a pattern sharp alternating zigzag bends.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh

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SUPERVISORY PATENT EXAMINER
12/22/06.